K010194

FEB 1 5 2001

510(k) SUMMARY

Recliner Care Inc.
Model: Comfor-Cliner Manual Wheelchair

Submitter: Recliner Care Inc.
122 Avenida Del Sol
San Antonio, Tx 78232

Phone: 210-496-0915
Fax: 210-496-0915

Contact Person: Mark D. Brown

Date Prepared: January 10, 2001

Name of Device: Comfor-Cliner

Common Name: Manual Wheelchair

Classification: Wheelchair, Mechanical – 890.3850

Predicate Device: World Class Wheeled Chair (K984457)
By: Suiter Medical

Description of Proposed Device:

The Comfor-Cliner is a manual wheelchair designed to provide mobility for individuals who can not sit in an upright position for long periods of time. The seat back reclines for a more restful position and the seat bottom swings forward to keep the center of weight safely between the wheels.

The reclining function is controlled by two release levers located on the handles at the rear of the wheelchair. When the two levers are squeezed, flexible cables from the levers release the mechanical locks under the chair which allow the seat and seat back to rotate to the desired position. When the levers are released, the mechanical locks engage and hold the desired position.

The construction is welded aluminum tubing common on many wheelchairs. The frame is a rigid, "non-folding" design with a solid seat and back, compatible with various cushions currently available on the market. Standard large wheels are used on the back and conventional castors are used on the front.

All upholstery used on the Comfor-Cliner meets the requirements of NFPA 260B standard for flame retardant.

510(k) SUMMARY (continued)

Intended Use:

The intended use of the Comfor-Cliner is to provide mobility to persons limited to a sitting position but unable to sit in an upright position for long periods of time.

Comparison of Device Characteristics to Predicate:

The Comfor-Cliner has the same technological and performance characteristics as the predicate device. Both wheelchairs are manually propelled and manually reclined. Both are constructed with a welded tubular frame with large rear wheels and smaller pivoting castors in the front for turning. The intended purpose of both wheelchairs is to provide mobility to non-ambulatory persons who need to recline to reduce discomfort.

The Comfor-Cliner differs from the predicate device in the method and means of reclining and in the type of armrest. The predicate device uses a pneumatic cylinder to control the reclining motion while the Comfor-Cliner uses release levers on the handles to release a mechanical lock. Also, the Comfor-Cliner has a mechanical linkage to coordinate the motion of the seatback, seat bottom angle and legrest angle while the predicate device does not. The armrest is fixed on the Comfor-Cliner while the armrests on the predicate device are adjustable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2001

Mr. Mark Brown
Recliner Care, Inc.
122 Avenida Del Sol
San Antonio, Texas 78232

Re: K010194
Trade Name: Comfor-Cliner
Regulatory Class: I
Product Code: IOR
Dated: January 10, 2001
Received: January 22, 2001

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K010194

Device Name: Comfor-Cliner

Indications For Use:

The intended use of the Comfor-Cliner is to provide mobility to persons limited to a sitting position but unable to sit in an upright position for long periods of time. Conditions for which the Comfor-Cliner is indicated are:

Cerebral Palsy	Muscular Dystrophy	Multiple Sclerosis
Head Injury or Trauma	Geriatric Conditions	Quadriplegic
Spina Bifida	Arthritis	Paraplegic
Polio	Amputee	And other debilitating Conditions

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per21 CFR 801.109)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010194

(Optional Format 1-2-96)